UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

| | | |
|---|---|---|
| UNITED STATES OF AMERICA, | ) | |
| v. | ) | Criminal No.: 14-cr-10363-RGS-7 |
| (7) SHARON P. CARTER, | ) | |
| Defendant. | ) | |

**REPLY MEMORANDUM IN SUPPORT OF SHARON CARTER'S MOTION FOR JUDGMENT OF ACQUITTAL OR, ALTERNATIVELY, A NEW TRIAL**

With leave of the Court, Sharon Carter submits this memorandum to respond to the Government's Opposition to her motion for judgment of acquittal or, alternatively a new trial.

## I. THE GOVERNMENT CITES TO NO EVIDENCE SUFFICIENT TO FIND THAT MS. CARTER KNOWINGLY AND WILLFULLY JOINED COUNT 3's CHARGED CONSPIRACY

The Government points to no evidence sufficient to conclude, beyond a reasonable doubt, that Ms. Carter knew of the existence of any agreement to deceive, obstruct and impede the FDA's exercise of regulatory oversight over NECC, or that she willfully joined in that agreement with the specific intent of facilitating its unlawful purpose. The arguments it advances on this point are unavailing, for the following reasons:

1. Despite the Government's expansive view of Ms. Carter's duties at NECC (Opp. at 3-5), none of those duties involved regulatory matters. The Government responds that it need not prove Ms. Carter's direct involvement in such matters, because she is liable for actions taken by her co-conspirators in furtherance of the conspiracy whether she personally participated in them or not. (Opp. at 12-14). This assertion misses the point. Indeed, it presumes the very fact the Government was required – but failed – to establish. To hold Ms. Carter liable for actions

taken by others in furtherance, the Government first must prove Ms. Carter's joinder and membership in the underlying conspiracy. A person cannot join something that she does not know exists. The Government's Opposition cites to no evidence introduced at trial – because there was none – that Ms. Carter knew anything about NECC's communications with state or federal regulators, including whether such communications were truthful or untruthful, intended to deceive or obstruct, or otherwise. Absent evidence of such knowledge, there was no basis on which to find that Ms. Carter knowingly and willfully joined in a conspiracy to make misrepresentations to the FDA for the purpose of evading federal regulatory oversight of NECC.

2. The Government cannot patch this hole in its evidence by contending that NECC's "need[]" for prescriptions was "widely known to NECC employees." (Opp. at 7). None of the testimony the Government cites for this proposition mentioned Ms. Carter. (Opp. at 7-8). Further, the quoted testimony expressed the belief of various employee witnesses that NECC needed patient names "because we were a pharmacy," not because NECC was *pretending* to be a pharmacy. *Id.*

3. The Government's citations to Exhibits 496 and 1007 are similarly unavailing. (Opp. at 5-6, 8). Of the many hundreds of exhibits introduced at trial, these appear to be the only two that the Government claims are somehow linked to Ms. Carter and that mention regulators or regulatory matters. Exhibit 496 is a Cadden e-mail addressed to Ms. Carter – and forwarded to order confirming staff – explaining that the number of units of medication per patient specified by customers on their order forms "must make sense" because "I [Cadden] must be able to logically explain to a regulator why we processed x# of units per patient." The e-mail contains guidance for use by NECC administrative staff when reviewing the information provided by customers on order forms. It says nothing about deceiving or defrauding the FDA.

Exhibit 1007 is a "Tech Manual" that Agent Mangiacotti testified was found at Ms. Carter's work station. Although the Government refers to the exhibit as "Carter's manual" (Opp. at 5), the Government introduced no evidence at trial concerning the origins of the manual (i.e., who created it, when, or why); how it came to be located at Ms. Carter's desk; or whether anyone ever saw Ms. Carter use it. Much of the manual is old, dating back as far as 1995 (Ex. 1007 at 82). And the "Compounding Legally" section quoted most heavily by the Government, which appears to have been authored in 1997-98, contains largely unexceptional information, including some statements that are actually *contrary* to the Government's prosecution theories, such as that anticipatory compounding is permitted; that office stock has historically played a valuable role in providing patient care; and that requirements "vary from state to state." (Ex. 1007 at 8, 76).[1] Whoever prepared the manual, and for whatever purpose, it furnishes no basis for finding willful joinder by Ms. Carter in a Cadden-initiated conspiracy – years later – to defraud the FDA.

4. Finally, the Government cannot rely on Ms. Carter's participation in NECC's patient name policies to support the jury's verdict on Count 3. Despite devoting a substantial number of pages to summarizing the evidence introduced at trial concerning these policies (Opp. at 8-12), the Government makes no effort to address the central proposition of *United States. v. Pappathanasi*, 383 F.Supp.2d 289 (D. Mass. 2005), or any of the other decisions cited by Ms. Carter in which courts have granted judgments of acquittal, or reversed convictions, on *Klein* conspiracy charges. (Mem. at 6-7, 12). As those decisions make clear, it is not enough for the

[1] The Government also cites to language from a 2005 self-inspection report signed by Cadden, not Carter, that references NECC procedures for controlled substance medications. (Opp. at 6, quoting language from Ex. 1007 at 25). NECC's controlled substance procedures were not at issue at trial. The Government does not explain how this passage has any relevance to Ms. Carter's culpability on Count 3. It does not.

government to rely on evidence that Ms. Carter (and others) participated in order processing practices that would have furthered the purpose of a conspiracy to obstruct the FDA if such a conspiracy existed and if Ms. Carter had joined in it. *Id.* (discussing cases). Rather, the government was required to prove beyond a reasonable doubt that such a conspiracy actually existed; that Ms. Carter knew of it; and that she knowingly and willfully joined in it with the specific intent of assisting it to accomplish its unlawful purpose. The government failed to meet this burden. It introduced no evidence that Ms. Carter was aware of a plan to deceive and obstruct the FDA much less that she knowingly and willfully joined in that plan with the purpose of helping it to succeed.[2]

5. To this last point, the Government responds "[t]here was no other reason" for NECC's patient name policies but to deceive the FDA. (Opp. at 12). This assertion is little more than a classic *ipse dixit*. It is wholly inadequate to prove Ms. Carter's guilt beyond a reasonable doubt. The statement also is contrary to the evidence at trial, which established that NECC's patient name policies were readily explainable in terms other than a willful motivation to obstruct the FDA. Specifically, the policies were just as fairly (and, indeed, more fairly) seen as establishing administrative guidelines for how to process customer orders that did not always list patient names, for reasons that included customer HIPPA concerns as well as the impossibility in certain circumstances of knowing specific patient identities in advance. (Mem. at 7-9). In the face of this evidence, the government bore the burden of introducing evidence sufficient to prove

[2] The Government's quotation of Samuel Penta's testimony, expressing Mr. Penta's view of Massachusetts law (Opp. at 8-9), has no relevance to Ms. Carter. There was no evidence that Ms. Carter knew of Mr. Penta's view, or that NECC's prescription practices allegedly violated Massachusetts law.

that Ms. Carter's purpose for participating in NECC's patient name policies was to defraud and obstruct the FDA. *Id.* (citing cases). It failed to do so.[3]

## II. THE GOVERNMENT MISCONSTRUES MS. CARTER'S "LEGAL IMPOSSIBILITY" ARGUMENT

The Government's Opposition misconstrues – and thus fails to address – Ms. Carter's "legal impossibility" argument.

Contrary to the Government's assertions, Ms. Carter does not contend that lawful activity cannot serve as evidence of a criminal conspiracy (Opp. at 15-16), or that conviction for a conspiracy to defraud requires successful completion of the planned fraud. (Opp. at 17). Rather, Ms. Carter has invoked the doctrine of "pure legal impossibility," which holds that a defendant cannot be convicted for conspiring to engage in conduct that was not a crime. (Mem. at 13-15).

Applied here, that doctrine precludes convicting Ms. Carter (or any other defendant) of conspiring to impede the FDA from exercising a function that the FDA neither possessed nor sought to exercise during the relevant time period. *Id.* Put somewhat differently, a *Klein* charge requires proof that defendants conspired to fraudulently obstruct, impair, or impede the lawful functions of a federal agency. If, as a matter of law, the agency in question did not have the authority to engage in the function that defendants allegedly conspired to impede, then defendants were conspiring to engage in conduct that was not a crime – i.e., to impair a "function" that the agency in question did not perform. Under the doctrine of legal impossibility, a conviction for such a "conspiracy" cannot stand.

---

[3] The Government's "no other reason" statement is further undercut by the jury's acquittal of co-defendant Alla Stepanets on Count 3. Had there truly been "no other reason" for NECC's patient name policies besides defrauding the FDA, the jury presumably would have convicted Ms. Stepanets – who also confirmed orders pursuant to those policies – on the Indictment's *Klein* conspiracy charge. It did not.

For all of the reasons set forth in Ms. Carter's initial brief, the FDA – by its own admission and as evidenced by its own conduct (i.e., its inaction) – neither possessed nor sought to exercise regulatory authority over the activities of outsourcing compounders during the time period in question (Mem. at 13-15). As a result, any alleged conspiracy to deceive the FDA from realizing that NECC was one of this new breed of outsourcing compounder cannot, as a matter of law, constitute a violation of the "defraud" clause of 18 U.S.C. § 37, because it pertained to a "function" that the FDA did not perform.

## III. THE GOVERNMENT FAILS FULLY TO ADDRESS MS. CARTER'S DUE PROCESS ARGUMENTS

The Government responds to Ms. Carter's due process arguments by citing precedent that Ms. Carter fully acknowledged. (Opp. at 18-19). The Government fails to address, however, the case-specific factors that give Ms. Carter's due process challenge particular force here. Specifically, the Government's Opposition does not respond to Ms. Carter's point that the statutory and constitutional infirmities discussed by the Supreme Court in *Skilling v. United States*, 561 U.S. 358, 402-13 (2010), are greatly magnified where, as here, the governmental "functions" allegedly impeded were "rife with uncertainty and ambiguity." (Mem. at 17). The First Circuit's existing precedent does not preclude this Court from concluding, consistent with *Skilling*, that Due Process prohibits Ms. Carter's conviction on Count 3 under these case-specific circumstances.

## IV. THE GOVERNMENT'S DISMISSIVE RESPONSE TO MS. CARTER'S MOTION FOR A NEW TRIAL IS MISPLACED AND UNPERSUASIVE

The Government responds dismissively to Ms. Carter's motion for a new trial, characterizing her request, alternatively, as "cursory" and "absurd." (Opp. at 19, 21).

Rhetoric, however, is no substitute for evidence or for well-grounded argument, and the Government's Opposition offers neither.

First, for all of the reasons Ms. Carter stated in her initial brief, the evidence the Government introduced against her on Count 3 was far from "abundant." (Opp. at 20). That the Government uses that word – repeatedly – does not make it so.

Second, it is no response to the prejudicial impact of the death- and patient-harm evidence to assert – as the Government does – that it could have introduced more. (Opp. at 20-21). The fact that the Government was precluded from introducing more does not alter the magnitude of the prejudicial impact caused by the evidence it *did* introduce.

Third, Ms. Carter's argument concerning the prejudicial impact of the Government's RICO evidence is far from "absurd." The jury heard weeks of testimony and received hundreds of exhibits about clean room operations that, put most charitably, were concerning. It was a clean room in which Ms. Carter never stepped foot. The evidence did not support convicting Ms. Carter on Count 2. The jury so found. There was no way, however, to counteract the substantial prejudice that introduction of the RICO evidence caused to the jury's ability to assess, impartially, Ms. Carter's guilt or innocence on Count 3. For all of the reasons set forth in Ms. Carter's opening brief, if the Court denies Ms. Carter's motion for judgment of acquittal, she requests, in the alternative, a new trial.

.

Respectfully submitted,

SHARON P. CARTER

By her attorney,

*/s/ Michael J. Pineault*

Michael J. Pineault (BBO 555314)
CLEMENTS & PINEAULT, LLP
24 Federal Street
Boston, MA 02110
Telephone: (857) 445-0133
mpineault@clementspineault.com

Dated: February 25, 2019

**CERTIFICATE OF SERVICE**

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing (NEF) and paper copies will be sent to those indicated as non-participants on February 25, 2019.

*/s/ Michael J. Pineault*
Michael J. Pineault